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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,783	08/09/2005	Yuji Matsuzawa	3083 US0P	9334

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TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
INTELLECTUAL PROPERTY DEPARTMENT
ONE TAKEDA PARKWAY
DEERFIELD, IL 60015

EXAMINER	
LIU, SAMUEL W	
ART UNIT	**PAPER NUMBER**
1656	

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06/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,783	MATSUZAWA ET AL.	
	Examiner	Art Unit	
	Samuel W. Liu	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-65* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

The preliminary amendment filed 1/10/2005 which amends claims 1-65 has been entered. The following Office action is applied to pending claims 1-65.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 1, 5, 9, 13, 17, 21, 25, 29, 33, 37, 41, 45 and 49, drawn to an isolated polypeptide, a pharmaceutical composition comprising the polypeptide, and a kit comprising the polypeptide.

Group 2, claims 2-3, 6-7, 10-11, 14-15, 18-19, 22-23, 26-27, 30-31, 34-35, 38-39, 42-43, 46-47, 50-51, 53 and 59, drawn to an isolated polynucleotide, a pharmaceutical composition comprising the polynucleotide, a diagnostic agent comprising the polynucleotide, and a kit comprising the polynucleotide.

Group 3, claims 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52 and 63, drawn to an isolated antibody, a pharmaceutical composition comprising the antibody, a diagnostic agent comprising antibody, and a kit comprising the antibody.

Group 4, claims 54 and 56-57, drawn to a method of screening for a compound having a specific affinity for the protein comprising use of the protein.

Group 5, claims 58 and 60-61, drawn to a method of screening for a compound changing the expression of the polynucleotide screening for said protein using the polynucleotide.

Group 6, claims 62 and 64-65, drawn to a method of screening for a compound changing the amount of the protein on a cell membrane or in an extracellular fluid comprising screening for the protein using the isolated antibody which binds to said protein.

The inventions listed as Groups 1-6 do not related to a single general invention concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups 1-3 are patentably distinct from one another because of the materially different structures of the biopolymers claimed. The Group 1 is drawn to the polypeptide, Group 2 to the polynucleotide whereas Group 3 to the antibody. Groups 4, 5 and 6 are drawn to the process of using the product claimed of Group 1, 2 and 3, respectively. Thus, each of the product/composition of Groups 1-3 is patentably distinct from one another. These products/compositions are capable of separate manufacture or use. The methods of Groups 4-6 as claimed do not overlap in scope, i.e., are mutually exclusive; are not obvious variants; the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect, e.g., mode of action of the antibody in the method of Group 6 is distinct from that of the polypeptide (the method of Group 4) and that of the polynucleotide (the method of Group 5). Thus, there is no claim(s) that constitutes a special technical feature linking all claims, as defined by PCT Rule 13.2 and 37 CFR 1.475(a), as a single contribution over the art, and a holding of lack of unity is therefore proper.

Additional Election

Regardless of the elected group, applicant is required under 35 US 121 (1) to elect a single disclosed composition to which claims are restricted.

Note that each chemical substitution results in different/distinct structure and mode of chemical reaction.

(i) If Group 1 or Group 4 is elected, applicant is required to elect one amino acid sequence with sequence identifier from claims 1, 5, 9, 13, 17, 21, 25, 29, 33, 37, 41, 45 and 49, because the amino acids sequences of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20 and 22 are distinct/differ from one another (note that SEQ ID NO:4 is not a fragment of SEQ ID NO:2 [see residue 114-136 of SEQ ID NO:4], and SEQ ID NO:8 is not fragment of SEQ ID NO:6 because they differ in signal peptide section).

(ii) If Group 2 or Group 5 is elected, applicant is required to elect one nucleotide sequence with sequence identifier from claims 2-3, 6-7, 10-11, 14-15, 18-19, 22-23, 26-27, 30-31, 34-35, 38-39 and 42-43, because the nucleotide sequences encoding SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20 and 22 are distinct/differ from one another.

(iii) If Group 3 or Group 6 is elected, applicant is required to elect one antibody from claims 4, 8, 12, 16, 20, 24, 28, 32, 36, 40 and 44, because the antibodies that bind to the protein of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20 and 22 are distinct/differ from one another.

It should be noted that this additional election of the restriction requirement is not species election but rather the additional election under 35 USC 121 because of the reasons stated above, and because the amino acid sequences discussed above, the polynucleotide encoding the corresponding amino acid sequences, thereof and the antibodies that binds too the corresponding amino acid sequences thereof are structurally and functionally distinct/different from one another.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The examiner can normally be reached Monday-Friday 9:00 -5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon, can be reached on (571) 272-0931. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

SWL

Samuel W. Liu, Ph.D.
Patent Examiner, AU 1656
May 1, 2007

ROBERT A. WAX
PRIMARY EXAMINER